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(54) SURGICAL DRAPE OR GOWN

(71) We, JOHNSON & JOHNSON, a Corporation organised under the laws of the State of New Jersey, United States of America, of 501 George Street, New Brunswick, New Jersey, United States of America, do hereby declare the invention for which we pray that a patent may be granted to us and the method by which it is to be performed to be particularly described in and by the following statement:—

This invention relates to surgical products.

More particularly, this invention relates to disposable surgical drapes having improved physical properties.

Surgical drapes or gowns are employed for various aseptic purposes. For example, during typical surgical procedures a patient is covered with one or more fabric drape sheets, surgery being carried out through apertures provided by the arrangement of the sheets or through fenestrations in the sheets themselves.

The main purpose of employing drapes or gowns is to attempt to minimize the risk of infection through the prevention of bacterial migration to the operative site. To this end, a primary requirement of the drapes or gowns is therefore that they provide a physical barrier between aseptic or sterile areas and contaminated zones, and provide a sterile field or surface surrounding the operative area. It is essential that the nature of the physical barrier provided by the draping sheet be such as to prevent communication by fluids between sterile and non-sterile areas. Such fluid communication provides a ready passage for the undesirable transmission of organisms.

Traditionally draping sheets have consisted of woven absorbent fabrics which of course are readily penetrated by fluids and in fact spontaneously conduct fluids between sterile and non-sterile surfaces. Thus, in order to prevent bacterial migration and transmission through fluid channels, it is necessary to commence an operative procedure with multiple layers of the absorbent fabric and periodically renew the fluid barrier thereafter by adding additional layers of dry sterile fabric over existing layers as they become soaked through with blood or other body fluids and solutions.

For the above reason, amongst others, the prior art technique of employing drapes or gowns of linen or similar absorbent material is being discontinued. Recently, the art has turned to the use of disposable fabrics of various types, chemically treated to render them water-repellent and thus reduce some of the disadvantages of linen type drapes. As is well known, such materials do possess the desirable attribute of being water-repellent, thus aiding in preventing the transmission of bacteria from contaminated zones to sterile or aseptic areas, such as would occur if the drape were to become wetted through from various solutions or external agents, e.g. wet laparotomy sponges.

However these materials do not provide a positive fluid barrier since they are permeable to gases and liquids through the physical interstices inherent in their structure. Thus the barrier property of such fabrics can be more or less readily overcome as the result of the physical penetration of fluids due to prolonged contact with the fluid or under the pressure of wetted objects allowed to rest on or contact the sheet. Further, repeated manipulation or scuffing of such sheets, particularly in the presence of moisture, can readily lead to a breakdown of the fluid barrier. It should also be noted that such fabrics may be readily permeable to certain non-aqueous liquids such as alcohol-based solu-

[*Price 25p*]

tions commonly used as adjuncts to surgical procedures, which is highly undesirable. Additionally, a further disadvantage with repellent treated fabrics is that they cause liquids to run off and disperse in a totally uncontrollable manner — for example as would occur in the case of water being placed on wax paper; while on the other hand liquids that do not run off remain in a puddle if they do not penetrate the drape material. Such uncontrolled dispersion of liquids frequently results in wetting of the garments of the operating team, the floor, etc.

In an effort to avoid these above remaining disadvantages draping fabrics have been constructed with totally waterproof layers consisting of non-porous plastics films. Polyethylene, polypropylene and similar films have been employed in this regard.

The use of such films, while avoiding one problem, creates another problem in that due to their inherent nature, they tend to entrap and condense the moisture vapour given off by the patient's body, thus forming a hot "clammy" and uncomfortable condition after a short period of use. To attempt to overcome this problem, it has been suggested that such drapes be provided with absorbent layers on one or both surfaces, the absorbent layers being adapted to absorb and hold fluids on both the sterile and non-sterile surfaces of the drape. However the inclusion of such a fluid absorbent layer on the patient-contacting surface of the drape does not eliminate this problem but merely delays its onset until such time as the fabric approaches the saturation point.

In accordance with this invention, there is provided a drape structure which not only overcomes the problems of the prior art absorbent drapes in eliminating the possibility of fluid communication between sterile and non-sterile surfaces but further alleviates the hot "clammy" and uncomfortable condition generated by prior art "waterproof" drapes. The drape of the present invention achieves these objectives while at the same time retaining the desirable characteristics usually associated with such materials — i.e. sterilizability and flexibility (drapability).

According to the present invention there is provided a surgical drape product having a moisture vapour transmission rate characteristic equivalent to at least 15 grams water/square meter/24 hours according to ASTM test E 96-66(B) and comprising a sterilizable, flexible, waterproof, water-insoluble, non-toxic, non-microporous film or sheet substrate having a pair of opposed major faces, and a sterilizable, non-toxic, flexible absorbent covering layer in juxtaposition with at least one of said major faces of said substrate.

According to an embodiment of the present invention the surgical drape product has a moisture vapour transmission rate characteristic equivalent to at least 30, preferably, 60 grams of water/square meter/24 hours according to ASTM test E 96-66(B).

We have found that when employing substrates having the above-defined characteristics, there is a marked improvement in the usefulness and physical characteristics of the drape structures. Thus, for example, the drape structure prevents fluids from being transmitted from a "top" or sterile surface of the drape to non-sterile areas; moreover, fluids such as perspiration cannot be transmitted from the reverse (bottom) side or "patient's" side of the drape to the sterile side. Thus, penetration of fluids through the drape in either direction is avoided to prevent the formation of fluid "channels" for the transmission of bacteria, thereby minimizing the possibility of infection. Still further, body perspiration accumulating on a patient can evaporate thereby providing a further desirable characteristic.

Experiments reported in the literature have shown that the human body at rest has a varying degree of insensible moisture vapour loss rate, depending on the specific part of the body. In recent literature, moisture vapour loss has been indicated to be about 50 to 72 grams/square meter/24 hours (see "Measurement of Transepidermal Water Loss by Electrical Hygrometry", by H. Baker et al, page 441, Arch Derm-Vol 96, October 1967), and about 120 grams/square meter/24 hours (see "The Regeneration Rate of the Water Vapour Loss of Heavily Damaged Skin" by D. Spruit et al, page 117, of the publication of the 169th Meeting Netherl. Soc. Derm., Nijmegan 1964 Dermatologica 132:115-123 (1966)); with generally accepted figures of between 50 to 75 grams vapour loss/square meter/24 hours being more representative for the trunk of the human body, under conditions which would normally be encountered by the body, during, for example, surgical procedures.

The materials which may be employed as the substrate components for the drape products of the present invention may be any suitable sterilizable, non-adhesive, non-microporous, substantially water-insoluble, and preferably alcohol-insoluble, material in the form of sheets or film. Such materials are preferably one-piece, continuous layers having opposed major surfaces with a relatively minor thickness in comparison to the length or width of the

surfaces, and may be in the form of blown or expanded films or sheets or alternately, unfoamed or nonexpanded materials. Still further, the substrate may form an integral component of the overall total structure of the products as for example, where the substrate is extrusion coated or cast on the covering layer, such products being particularly suitable where the covering layer has absorbent characteristics.

Typical examples of materials which may be used are one-piece continuous sheets or films of the following compounds, the numerical values having the subsequently described meaning; cellulose acetate (465-620), cellulose triacetate (465-620), cellulose acetatebutyrate (465-620), polyurethanes (e.g. polyurethane elastomer 165-275), regenerated cellulose (up to 500), ethyl cellulose (up to 55), modified (e.g. plasticized) polyvinyl chloride, polyamide (e.g. Nylon), collagen, gelatin, ethylene/vinyl acetate copolymers, and cellulose propionate. The above numerical values of the various types of sheets or films which may be used as the substrate layer are the approximate moisture vapour transmission rate values for a 1 mil thickness of the substrate, calculated according to ASTM test E 96-66(B). These values will vary depending on the thickness of the substrate layer and where sheets or films of .5 mil thickness are employed the values will be approximately doubled; conversely, on the other hand, the above moisture vapour transmission rate values will generally decrease as the film thickness increases for a given type of film composition. Thus, in the embodiments of the present invention, the substrate layer is selected so that at any given thickness, the total layer has a minimum moisture vapour transmission capacity of at least 15, and more preferably at least 30 to 75 grams of water/square meter/24 hours according to ASTM test E 96-66(B).

Particularly preferred as the substrate material for the products of the present invention is plasticized or otherwise modified polyvinyl chloride, due to its ready availability and economic attributes. That marketed under the trade mark "VINYLITE MW FILM" which is a non-porous polyvinyl chloride material having a moisture vapour transmission rate according to ASTM test E 96-66(B) of 109 grams/24 hours/square meter for a 0.7 mil thickness is one preferred material which has been found to be desirable. The above materials may be produced by conventional procedures and modified if necessary to provide the essential characteristics for the products of the present invention. To this end, the conventional materials may be modified by incorporating therein a non-toxic plasticizing or similar agent to impart to the materials the required moisture vapour transmission rate characteristics.

It will be understood that the degree to which any of the above materials may be plasticized or modified to provide the required moisture vapour transmission rate characteristics may be to an extent several times the moisture vapour transmission rate factor of the human body — in the case of polyurethane film, some types have moisture vapour transmission rate measurements of 200 to 340 grams/square meter/24 hours/mil of thickness according to ASTM test E 96-66(B) and in the case of plasticized cellulose acetate, depending on the thickness of material, ranges equivalent to from 650 to 1,000 grams moisture vapour/24 hours/square meter for a 1 mil thickness of material can be obtained, according to measurements by ASTM test E 96-66(B).

For reasons of economy and drapability, the thickness of the substrate is preferably kept to a minimum consistent with physical strength requirements and the above-described moisture vapour transmission rates. Increased thicknesses for the substrate would not serve any useful purpose. Typically, the thicknesses may vary between one-quarter mil to several mils, e.g. 5 to 6 mils or higher, depending on the type of material employed.

According to a preferred embodiment of the present invention, the substrate chosen preferably is one having a sufficient degree of durability and abrasion resistance in both the wet and dry states, so as to avoid disintegration upon normal processing and handling. Further, the drapability characteristics of the substrate are preferably chosen so that the finished drape sheet substantially conforms to all major contours of th human body and to any other object which may be encountered during use — e.g. an operating table. A further preferred characteristic of the finished product is that it does not include any loose fibers or foreign matter on its surface which could potentially enter a wound or incision as an undesirable foreign element.

The size and shape of the product may vary according to conventional practices; in the case of laparotomy or similar drapes, suitable apertures or fenestrations may be provided for providing access to the incision site.

The substrate sheet component of the products of the present invention may also include conventional additives usually associated with drapes or gowns — e.g. non-toxic colouring agents, bacteriostats, anti-static agents, flame retardants, and stabilisers, again consistent with the substrate having the above-defined moisture

vapour transmission rate characteristics.

The term "waterproof" is used in the present specification to denote materials which are incapable of transmitting liquid phase water through their structure. To this end, the substrate material of the present invention is non-microporous since it has been found that a microporous film substrate tends to transmit liquid phase water through its surface when subjected to pressure as may be encountered during the use of drape products. Still further, the substrate material should most desirably be a continuous one-piece film or sheet for most uses.

The covering layers, depending on the type of surgical drape being contemplated, will also have the characteristics of being sterilizable and drapable or flexible, so as to permit the combined substrate and covering layer to conform to the contours of the human body.

For surgical drape use, the covering layer on at least one face will be a one-piece continuous, absorbent layer of suitable sterilizable material such as, for example, wood pulp fibers, knitted or woven fabrics, cellulose tissue or non-woven fabrics, preferably substantially coextensive with at least the area of the drape intended to cover a patient. The thickness of the absorbent layer may vary according to different factors, e.g. the absorption capacity desired, as well as economics of the product. As an example, using non-woven fabric as the absorbent layer, typical weights will be from one hundred to several thousand grains per square yard, and where absorbent covering layers are applied to both faces of the substrate, different weights may be used on each side. In preferred embodiments of the above, the other face of the surgical drape is provided with a liquid repellent, vapour permeable covering layer in combination with the opposed face being an absorbent layer. In a further embodiment, both faces are provided with an absorbent layer.

When one face of the substrate is covered with a liquid repellent, vapour permeable covering layer, the layer may be made of various types of suitable material. Such materials are for example, liquid repellent, vapour permeable woven and non-woven fabrics, woven fabrics being e.g. gauze, linen; cellulose tissue or open-celled foam which is liquid repellent but vapour permeable. The repellent layers most desirably function so as to hold any liquids "in place" without permitting their spread from site to site — i.e. the repellent layer is one which does not spontaneously transmit liquids from site to site — in order to maintain and preserve the sterility of the drape. It preferably has the property of being non-slippery — i.e. it frictionally engages the surfaces of the patient to prevent slipping. Additionally, the repellent layer must be sterilizable and non-toxic. When the repellent layers are included in the products of the present invention, they are normally intended to be placed on the "patient's" side of the drape, and for this reason possess the characteristics of being porous or highly permeable to vapours to permit the transmission of vapours through the substrate layer.

The use of an absorbent covering layer contributes to an additional desirable characteristic of the drape — the reduction of the glare factor, whereby it reduces the glare which may be reflected from the substrate depending on the type of substrate material used.

In choosing the absorbent or repellent covering layer, the choice of material is most desirably such that the moisture vapour transmission rate of the overall drape structure is not significantly impeded. The covering layer may be applied by different methods to the major faces of the substrate as desired and for the above reasons, in securing the covering layer to the substrate, as e.g. by bonding, it will be understood that the method and nature of the bonding is chosen so as to retain to a substantial degree the required moisture vapour transmission rate characteristic of the substrate. To this end, the covering layer may be secured to the substrate by any conventional method such as heat-sealing, stitching or adhesives; or in the alternative, the substrate may be coated onto the covering layer as for example, by emulsion or solvent system techniques by casting of a plastisol or extrusion coating, etc. In the case of adhesives, the adhesive chosen will be one which is sterilizable and abrasion resistant, and will be applied most desirably by employing a uniform or random bonding technique; in the latter case, the substrate is provided at random points with the adhesive to secure the absorbent covering layer to the substrate. A typical adhesive which may be used is a plastisol made using a powder resin such as that marketed under the trade mark "GEON 121" and a plasticizer such as dioctyl phthalate. In the alternative, if a pattern other than random point bonding or intermittent bonding is employed, the adhesive must be one which has a moisture vapour transmission rate permitting the substrate to retain the required moisture vapour transmission rate characteristics. In the case of stitching the penetration of the waterproof plastic layer by stitches may be permitted in areas of the product significantly remote from areas desirably protected from con-

tamination — e.g. stitching around the periphery of a sheet would be acceptable. Where stitching is not desired, the waterproof layer may be applied as an extruded coating or cast film, to the absorbent covering layer.

Similarly, in the case of heat-sealing, bonding should be on an intermittent basis — e.g. again preferably on a random intermittent basis, to retain the 15% minimum moisture vapour transmission rate characteristic and must be carefully controlled so as to prevent rupture of the film.

It will be appreciated, within the context of the present invention, that multiple layered products may be prepared, wherein adjacent layers of covering materials are separated by a layer of the substrate, to form a multi-layered product with varying characteristics.

A particularly preferred drape product of the present invention which has been found very suitable for use as surgical drapes includes a continuous one-piece substrate layer having a thickness of e.g. between 0.5 mil and 1 mil of plasticized polyvinyl chloride having a moisture vapour transmission rate equivalent to approximately 77 grams moisture vapour/square meter/24 hours for a 1 mil thickness film according to ASTM test E 96-66(B); typical values of the total moisture vapour transmission per se for the above film thicknesses of 0.5 mil to 1 mil being from 155 to 77 grams water/square meter/24 hours according to ASTM test E 96-66(B). This preferred drape is provided with opposed substantially coextensive facings of either nonwoven absorbent fabric or opposed faces of a nonwoven absorbent layer and a liquid repellent, vapour permeable layer, secured thereto by, for example, adhesive print bonding in such a manner so as not to substantially impair the moisture vapour transmission rate of the polyvinyl chloride substrate. The nonwoven facings may be of the same or different weights and hence varying degrees of absorbency. Still further, the products of the present invention may include one or more layers of scrim material — that is, material which provides a reinforcing structure for the drapes or gowns.

The products of the present invention provide a fool-proof non-leaking fabric, useful as various types of drapes as, for example, those which are employed in what is known in the art as a "surgical pack". Such surgical packs are made up of various types of drapes including e.g. laparotomy sheets. Other uses of the products of the present invention include drapes for tray covers or liners and underbuttocks drapes as for example disclosed in Canadian Patent 809,439. The products may also be converted into various types of other articles as for example surgeons' gowns, scrub suits, scrub dresses and similar items wherein the drape structure may form at least a portion of the product. Similar uses include operating room shoe covers, linen protectors, caps, pillow cases and bibs.

Having thus generally described the invention, reference will now be made to the accompanying drawings illustrating a preferred embodiment and in which

FIGURE 1 illustrates a perspective view of a drape product according to the present invention, and including an optional feature wherein the drape is provided with a pattern of hydrophobic lines thereon;

FIGURE 2 is an enlarged section taken along the line 2-2 of Figure 1 showing the construction of the drape of Figure 1; and

FIGURE 3 is a top plan view of a portion of a drape similar to Figure 1 showing a modified optional embodmient of a pattern of hydrophobic lines on the drape.

In the drawing, there is illustrated in Figures 1 and 2, a portion of a preferred surgical drape product indicated generally by reference numeral 10 and including a flexible one-piece continuous substrate layer 12 of plasticized polyvinyl chloride film (see Figure 2). Layer 12 is approximately .7 mil in thickness, and per se has a total moisture vapour transmission rate of 109 grams/24 hours/square meter according to ASTM test E 96-66(B), equivalent to approximately 75 grams moisture vapour/square meter/24 hours for a 1 mil film thickness according to ASTM test E 96-66(B). In the embodiment shown, the particular type of drape shown is characterized by having a substantially rectangular configuration, and a centrally located aperture 14 forming a surgical fenestration for use when the drape is placed on a patient.

The drape illustrated includes continuous, one-piece upper and lower layers of absorbent nonwoven fabric indicated by reference numerals 16 and 18 respectively, substantially coextensive with and adhesively secured to the polyvinyl chloride layer 12 by means of print bonding. The nonwoven layers in this case have a weight of approximately 500 grains per square yard, and are substantially coextensive with layer 10, resulting in a product having approximately 80 grams-square meter/24 hours according to ASTM test E 96-66(B).

A further preferred drape according to the present invention is substantially similar to that illustrated, but in this case is provided with an absorbent nonwoven

fabric layer 16 on one surface and on the other a liquid repellent, vapour permeable layer 18 constructed in the above manner.

In Figure 3, the drape construction is substantially identical to that of Figures 1 and 2, but is modified slightly as to the provision of hydrophobic lines or patterns thereon as hereinafter described.

In use, the particular drape illustrated, after sterilization by any suitable conventional technique, may be employed for surgical purposes in e.g. operations. With a two-sided absorbent type drape of the type illustrated, either side may be placed in contact with the patient. Thus, as described hereinbefore, with a drape of the above type, the penetration of fluids through the drape, in either direction, is avoided while permitting evaporation of the patient's perspiration.

In the drawings, the drape product illustrated has been modified to include hydrophobic lines or areas thereon. To this end, hydrophobic lines may advantageously be incorporated on drape products such as that claimed herein, which act as "dams" or "barriers" for controlling the spread or dispersion of body or other fluids on a drape. To this end, the drape of Figure 1 has a plurality of hydrophobic, fluid repellent coatings in the form of spaced-apart macroscopically continuous lines 20 extending in the longitudinal direction. As illustrated, lines 20 are substantially coextensive with the drape, and serve as barriers to the spread of fluids. The hydrophobic lines 20, in the specific construction shown, are only provided on the outer side of the drape; thus, in the case of spilling fluids onto the outer surface of the drape during e.g. surgical procedures, the lines 20 will localize the spreading of the fluid while at the same time, the construction of such a drape according to the present invention prevents the fluid from being transmitted to the other side. Moreover, such hydrophobic coatings tend to prevent or control any liquid from spreading towards the sides of the drape adjacent the positions occupied by the surgical team and thus prevent contamination of the surgical team's sterile gowns.

Figure 3 illustrates a drape of similar construction to that of Figures 1 and 2 but showing a modified pattern of hydrophobic lines on the drape. In this case, the drape indicated generally by reference numeral 22 includes spaced-apart opposed pairs of parallel hydrophobic lines 24 and 24' forming rectangular patterns on the upper surface of the drape, the rectangular patterns being of increasing area extending outwardly from the center of the drape. The hydrophobic lines may be of any suitable material commensurate with providing suitable barrier outlines onto the drape. Typical examples of such materials include e.g. those products marketed under the trade marks "PHOBOTEX FTC", "PHOBOTEX FTA", "PARAMUL DC 1", "PARAMUL DC 2", "SCOTCHGUARD", (in which the preceding trade marks denote various types of proprietory compositions of a hydrophobic nature) and various other hydrophobic compounds such as silicons, rubbers, plastics and vegetable or mineral waxes. The material forming the hydrophobic lines should of course be non-toxic, sterilizable, non-irritating and non-allergenic with preferably little or no affinity for water or other fluids which it may come into contact with.

The hydrophobic lines may be applied by any suitable means and method such as coating by means of passing the drape in contact with engraved rollers. The width of the hydrophobic lines may vary within wide limits although typical practical values are from .015 to .25 inch.

WHAT WE CLAIM IS:—

1. A surgical drape product having a moisture vapour transmission rate characteristic equivalent to at least 15 grams water/square meter/24 hours according to ASTM test E 96-66(B), and comprising a sterilizable, flexible, waterproof, water-insoluble, non-toxic, non-microporous film or sheet substrate having a pair of opposed major faces, and a sterilizable, non-toxic, flexible, absorbent covering layer in juxtaposition with at least one of said major faces of said substrate.

2. The product of claim 1, having a moisture vapour transmission rate characteristic equivalent to above 30 grams water/square meter/24 hours according to ASTM test E 96-66(B).

3. The product of claim 2, having a moisture vapour transmission rate characteristic equivalent to above 60 grams water/square meter/24 hours according to ASTM test E 96-66(B).

4. The product of claim 1 or claim 2, wherein said substrate consists of cellulose acetate, cellulose triacetate, cellulose acetatebutyrate, collagen, gelatin, polyurethanes, polyvinyl chloride, ethylene/vinyl acetate copolymers, polyamide, cellulose propionate, regenerated cellulose or ethyl cellulose.

5. The product of any one of the preceding claims, wherein said covering layer is secured to the face of said substrate by uniform or random bonding

6. The product of any one of the preceding claims, wherein said absorbent layer is on both of said major faces and substantially coextensive therewith.

7. A surgical drape as claimed in claim 1 substantially as hereinbefore described with reference to the accompanying drawings.

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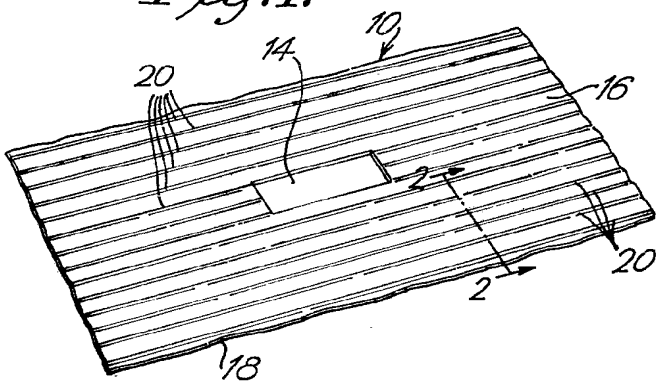
Fig.1.



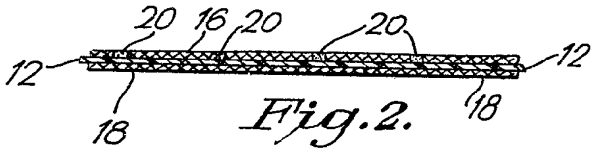


Fig.2.

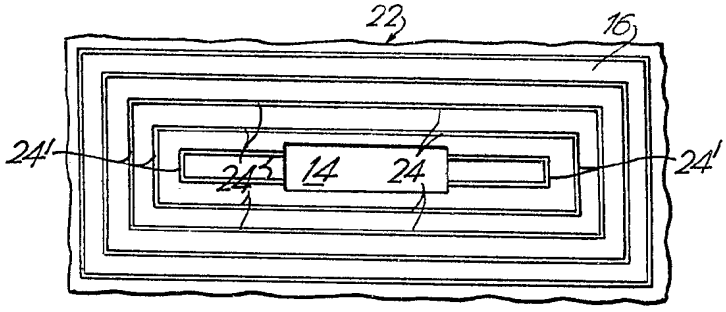


Fig.3.